

Does an app based short intervention improve quality of sleep?

Submission date 05/04/2019	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 08/04/2019	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/03/2023	Condition category Nervous System Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Two out of three adults in Germany have trouble sleeping at least occasionally, among employees the numbers rise up to 80%. Poor sleep quality can result in daytime fatigue and reduce performance, and is also associated with irritability and depressed mood. Only a few people with poor sleep quality seek professional help. Therefore, researchers have developed an app-based training to help people implement behaviour changes and improve sleep quality. The aim of this study is to find out whether this training helps improve sleep.

Who can participate?

German-speaking adults

What does the study involve?

Participants are randomly allocated to either receive access to the app-based training immediately or to wait for 6 months. The training is self-paced, but the recommended duration is 8 weeks (1 chapter per week). There are three assessments (start of the study, 8 weeks, 26 weeks).

What are the possible benefits and risks of participating?

Participants may improve their sleep quality. For some participants, thinking about their thoughts and feelings may be upsetting.

Where is the study run from?

Technische Universität Dresden, Institute of Clinical Psychology and Psychotherapy (Germany)

When is the study starting and how long is it expected to run for?

March 2019 to October 2020

Who is funding the study?

There is no external funding for the study

Who is the main contact?

Bianka Vollert

bianka.vollert@tu-dresden.de
(updated 03/07/2019, previously: Dr Ina Beintner
ina.beintner@tu-dresden.de)

Contact information

Type(s)

Public

Contact name

Ms Bianka Vollert

Contact details

Institute for Clinical Psychology and Psychotherapy
Chemnitzer Straße 46
Dresden
Germany
01187
+49 (0)351 463 38570
bianka.vollert@tu-dresden.de

Additional identifiers

Protocol serial number

1

Study information

Scientific Title

Refresh - Does an app based short intervention improve quality of sleep? A randomised controlled feasibility study

Acronym

REFRESH

Study objectives

The current study seeks to examine the acceptability and efficacy of an app-based short intervention (Refresh) to improve sleep quality compared to a waitlist control group in the general population. The hypothesis is that Refresh will be efficacious, with significant improvements of sleep quality within the intervention group and differences at post intervention and follow-up between the intervention group and the waitlist control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/03/2019, Ethikkommission (IRB) an der TU Dresden (Fetscherstraße 74, 01307 Dresden, Germany; Tel: +49 (0)351 458 2992; Email: ethikkommission@mailbox.tu-dresden.de), ref: EK 111032019

Study design

Single-center unblinded randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Poor sleep quality

Interventions

Method of randomisation: stratified block randomization (strata: gender, sleep quality (RIS total score <12 vs ≥12), use of sleep medication).

1. Refresh: an app-based short intervention to improve sleep quality
2. Waitlist control

The intervention is self-paced, but the recommended duration is 8 weeks (1 chapter per week). There are three assessments (baseline, post-intervention (+8 weeks), follow-up (+26 weeks)).

Intervention Type

Behavioural

Primary outcome(s)

Sleep quality is measured using the Regensburg Insomnia Scale (RIS) Total Score at baseline and post-Intervention (8 weeks)

Key secondary outcome(s)

1. Sleep quality is measured using the Regensburg Insomnia Scale Total Score at baseline and follow-up (26 weeks)
2. Depression symptoms are measured using the depression scale from the Patient Health Questionnaire (PHQ-9) Total Score at baseline, post intervention (8 weeks) and follow-up (26 weeks)
3. Acceptance of the training is measured using the Working Alliance Scale adapted for Online Interventions at Post Intervention (8 weeks) and usage of the intervention (during intervention period)

Completion date

31/10/2020

Eligibility**Key inclusion criteria**

1. Over 18 years of age
2. Fluent in German
3. Access to the Internet during the intervention period

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

371

Key exclusion criteria

1. Current treatment for depression
2. History of psychotic or bipolar disorder
3. Suicidal ideation

Date of first enrolment

15/04/2019

Date of final enrolment

31/03/2020

Locations

Countries of recruitment

Austria

Germany

Luxembourg

Switzerland

Study participating centre

Technische Universität Dresden, Institute for Clinical Psychology and Psychotherapy

Chemnitzer Straße 46

Dresden

Germany

01187

Sponsor information

Organisation

Technical University Dresden (Technische Universität Dresden)

ROR

<https://ror.org/042aqky30>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

After the main results of the study have been published, anonymised participant level data can be shared for individual patient data meta-analyses upon request to Dr Ina Beintner (Ina.Beintner@tu-dresden.de), stating the purpose and methods of the planned project. ICMJE authorship recommendations apply. Participants give consent that their anonymised data can be used in research cooperation projects.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	outcome measure results	21/03/2023	24/03/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes